Prototyping Novel Instruments for Fetal Surgery through Virtual Reality Simulation and 3D Printing

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***Abstract*—Designing novel medical devices is a complex matter. Involving clinicians as early as possible into the development process is of crucial importance; it helps to shorten the development cycle and increases the likelihood of later acceptance by clinicians. In this paper we show how through a combination of 3D printing and Virtual Reality simulation it is possible to involve clinicians in a very early stage, yet receive concrete quantitative and qualitative information that can shift the design to a more appropriate line of thought. Treatment of the Twin-to-Twin Transfusion Syndrome serves as a case study for this work. At present rigid endoscopes are used to direct a laser to treat the twin's placenta. We study here whether flexible endoscopes would be more appropriate. More in particular, we investigate whether one or two distal bending degrees of freedom would be advantageous and how they are to be handled by the surgeon. Preliminary experiments show a preference for a single distal bending degree of freedom, but without conclusive statistical evidence. From the results guidelines for future experiments have been derived.**

I. Introduction

The Twin-to-Twin Transfusion Syndrome (TTTS) is a pathological condition that occurs in monochorionic twins, when anastomoses at the level of the placenta create a transfusion between the twin fetuses. The donor is deprived from blood and nutrients, while the receiver has those in excess. The result is a life-threatening condition for both of them in severe cases. An effective treatment for TTTS is to access the amniotic cavity of the mother with a fetoscope, through the abdomen and uterus, and to photocoagulate the anastomoses with a laser [1, 2].

The entry point into the amniotic cavity ideally is directly opposite the placenta when using straight fetoscopes. However, in the case of anterior placenta placement this is not possible and it becomes difficult to visualize and effectively laser the anastomoses with a straight fetoscope. Consequently for anterior placentas significantly longer operating times have been reported [3]. Semi-rigid fetoscopes that are bent over 30 degrees, when inserted into a curved sheath, have been investigated for this reason, showing an improvement for treatment of TTTS in case of an anterior placenta [4]. While being thought to be beneficial for the surgical outcome, the use of a flexible and actively bendable fetoscope is commonly associated with large cognitive overhead. Amongst others, difficulty of orientation in space and assessment of the bending state of a bendable endoscope have been reported in literature [5] for other types of surgery.

In this paper we investigate the ergonomic aspects, usability and intuitiveness of the fetoscope interface (handle), when the surgeon is given control over one or two bending degrees of freedom (DoFs) at the tip of a fetoscope. In particular the mapping of the DoFs at the fetoscope interface to the DoFs at the fetoscope tip is investigated. To avoid that the results are dependent on the specific hardware and to facilitate data collection and analysis, the evaluation of the different interface mappings was carried out with the same physical handle in a virtual reality (VR) setup. The VR also avoids the need to actually build tip bending mechanisms, which would be complex and would unnecessarily fix parameters such as the bending range. Along similar lines as the study that Herman *et al.* conducted for needle driver instruments [6], a study is presented here that focusses on actively bendable endoscopes in fetal surgery.

Sec. II presents the dedicated interfaces that were developed in order to control the distal DoFs, as well as the virtual reality environment. Sec. III presents the user experiments and the results, and Sec. IV concludes the paper.

II. Virtual Reality Simulator for Fetal Surgery

The overall simulation environment is depicted in Fig. 1. This figure shows the sensorized fetoscope handle that was designed and 3D printed. The shaft of the fetoscope has a virtual tip that can be bent by controlling the two levers that are integrated in the fetoscope handle. A virtual camera is connected to the bendable tip. The fetoscope is inserted into a simulator box through a rubber interface at the insertion point. Using the data from the embedded sensors, a computer program determines the pose of the fetoscope camera and simulates the camera view upon a virtual surgical environment. The resulting fetoscopic image is being displayed on a computer screen right in front of the user as would be the case in a operating theater.

The prepared environment is a simplified representation of a TTTS placenta, designed in collaboration with clinicians to capture the essential parts of the procedure, but nothing more. To interact with it, e.g. to laser photocoagulate anastomoses of the virtual placenta, a foot pedal is used. Contact between instrument and placenta is not to be taking place, so the procedure does not require providing haptic feedback. The only interaction forces the user feels are coming from friction at the insertion point. Care has been taken that the rubber interface sheet generates friction similar to an insertion into tissue.

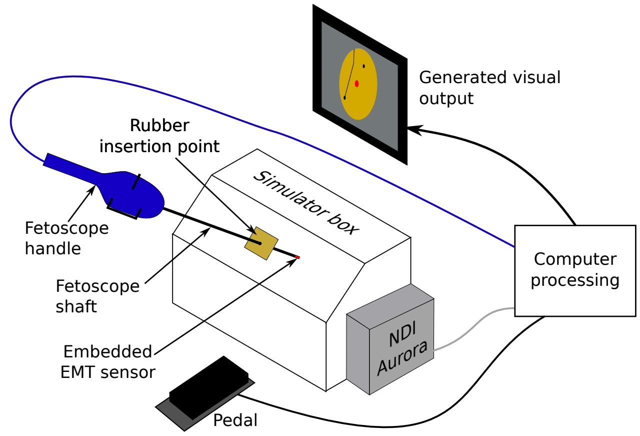

Figure 1. Overview of the simulation environment

A. Fetoscope design

The fetoscope consists of a handle and a shaft. The shaft is a simple rigid rod with a 6 DoF Electromagnetic Tracking (EMT) sensor (Aurora, NDI, Canada) embedded at the tip. The EMT data is used to measure the global pose of the fetoscope.

The fetoscope handle was created to have a comfortable grip. It contains two levers for user input which are easily accessible by the user's fingers The first design of the ergonomic was inspired by looking at commercial designs and from a study of several clay prototypes. The ergonomic handle design was obtained and produced using 3D printing. The two levers in the handle, that can be mapped in different ways to the bending DoFs of the fetoscope tip are connected to potentiometers that record their position and consequently determine the bending state of the fetoscope tip. Fig. 2 shows the fetoscope design with the position of lever 1 and lever 2 indicated.

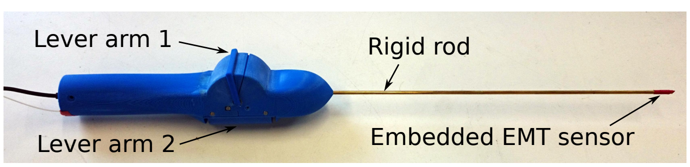

Figure 2. The developed fetoscope handle prototype

B. Virtual reality environment

The virtual reality environment makes use of the different available sensor inputs in order to compute the fetoscopic image that the user will see on the screen. The overal system relies on Robot Operating System (ROS)[1] for communication of messages between the different components, and uses the Visualization Toolkit (VTK)[2] for 3D computations and visualization.

1) Communication between components: The signals from the potentiometers, measuring the angles α of lever 1 and β of lever 2, are acquired through the analog input of an Arduino Micro board, that is integrated in the fetoscope handle. Pedal inputs arrive as digital inputs of an Arduino Uno board. Communication between the Arduino boards and the ROS core takes place using the rosserial library.

The data from the Aurora EMT sensor is received from the Aurora system, processed using the Open Robot Control Software (OROCOS)[3] and communicated at 40 Hz over the ROS messaging system.

A visualizer rosnode picks up the communicated sensor data and generates the video from the virtual camera that is located at the fetoscope tip.

2) Definition of frames and transformations: The virtual reality simulator needs to know the pose of the camera at the tip of the bent fetoscope with respect to environment. Based on the definitions of the coordinate frames in Fig. 3, this relation is called $\mathbf{T}_w^t$ or the transformation matrix between the world coordinate frame and the bent tip coordinate frame. $\mathbf{T}_w^t$ is obtained by composing several transformations:

$$\mathbf{T}_w^t = \mathbf{T}_w^a \mathbf{T}_a^i \mathbf{T}_i^t, \tag{1}$$

with $\mathbf{T}_w^a$ the transformation matrix between the world coordinate frame and the Aurora frame, $\mathbf{T}_a^i$ between the Aurora frame and the instrument frame, and $\mathbf{T}_i^t$ between the instrument frame and the bent tip frame.

As the Aurora field generator is rigidly attached to the simulator box, there is a fixed relation between the world coordinate frame and the Aurora coordinate frame. As such $\mathbf{T}_w^a$ was calibrated manually. $\mathbf{T}_a^i$ is directly measured by the Aurora tracking system. For computing $\mathbf{T}_i^t$ the angles α and β of the levers are used. The exact formulation of $\mathbf{T}_i^t$ depends on the selected interface mapping between the levers in the handle and the distal DoFs of the fetoscope. In the present work this is simply done by tilting the axis of view at the tip. For instance, if α corresponds to left/right tilting of the tip camera and β to up/down tilting, one can write:

$$\mathbf{T}_i^t = \mathbf{R}(\alpha, \mathbf{x}_t)\mathbf{R}(\beta, \mathbf{y}_t), \tag{2}$$

where $\mathbf{R}(\gamma, \mathbf{v})$ is an homogeneous rotation matrix of angle γ around the vector $\mathbf{v}$. Note that in our case, the $\mathbf{z}_t$ vector at the tip is defined as the tangent to the tip.

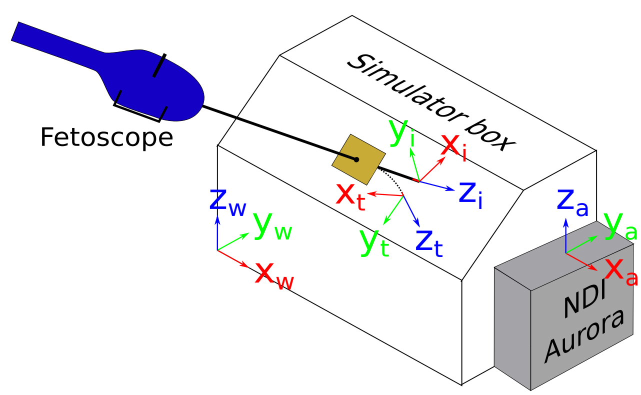

Figure 3. Overview of the different frames in the simulation environment: (x_w, y_w, z_w): world coordinate frame; (x_a, y_a, z_a): Aurora coordinate frame; (x_i, y_i, z_i): rigid instrument coordinate frame; (x_t, y_t, z_t): bent tip coordinate frame.

[1]www.ros.org
[2]www.kitware.org/VTK
[3]www.orocos.org

3) Environment: In order to test the ability and ease of the user to control his/her movements, a simplified, yet representative TTTS environment was designed. Similarly to, for instance, the FLS training system[4], the main idea is to provide an environment where the same gestures as during a real surgery can be done, but that does not offer overly realistic visual information. In this case, the surgical workflow includes finding the umbilical cord, identifying and lasering anastomoses on the vascular equator, and then connecting the laser dots in order to perform the solomonization [3].

In the virtual environment the anterior placenta is represented on two planes. The first plane is placed horizontally above the insertion point and the second plane opposite of the insertion point, at an angle of $120\,\mathrm{deg}$ with the first plane. A set of curved lines is textured on these planes mimicking the vessels. Target sites for anastomoses are indicated as numbered dots. The user must either follow vessels or laser anastomoses by pushing the foot pedal.

The fetoscopy visualization is simulated in VTK, using a virtual camera that is positioned at the origin of the bent tip coordinate frame. During procedural navigation, a green dot is projected from the camera onto the placenta to simulate the dot of the aiming laser. When the user pushes the pedal, the ablation laser is switched on. Ablation is simulated by simply adjusting the texture of the environment by adding red dots marking the positions were coagulation took place. Figure 4 shows different views upon the developed environment, before, during and after a user test.

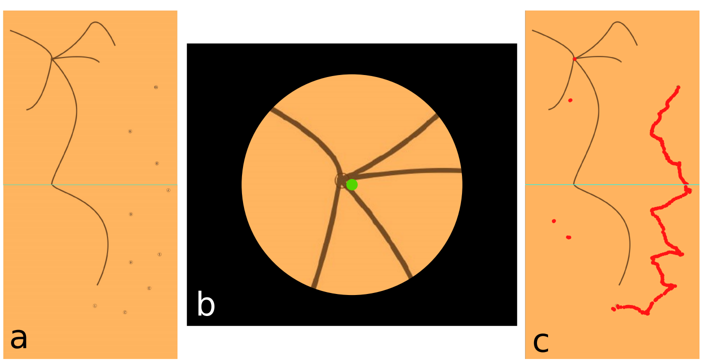

Figure 4. Views upon an example of environment. a: complete environment prior to testing; b: example of generated camera view, with the green dot showing the aiming laser; c: complete environment after testing. The red dots show the locations that have been lasered by the user.

III. Experiments

A set of user experiments has been carried out to compare the performance of two different fetoscope interfaces. In the *1 DoF interface* the fetoscope had 1 DoF at the distal tip: up/down bending. This DoF was controlled by lever 1 on the fetoscope handle. Other fetoscope motions come from gestures of the user's arm. The *2 DoF interface* introduced 2 DoFs at the fetoscope tip. Here lever 1 controlled up/down bending and lever 2 controlled left/right bending.

[4]www.flsprogram.org/

A. Test protocol

The test population consisted of a group of 22 novices with no experience in laparoscopy and an experienced surgeon. The lack of experience for the novices enabled to test for the intuitiveness of the interface. Every participant was asked to do a task in 3 different environments for both interfaces. The participants were divided into two groups. Group 1 (6 participants) alternated between both interfaces in the same environment, while group 2 (17 participants) switched interface after completing the task in three different environments.

Before the experiments the participants got an introduction to TTTS and the associated surgical workflow. During a trial period they could ask questions about the task (finding the umbilical cord, identifying and lasering anastomoses and finishing with a solomonization) and familiarize themselves with the test setup, until they felt comfortable with the fetoscope interface, the VR environment and the task. For the tests the participants were asked to be as precise as possible, while keeping in mind that time is also important. At the end the participants had to fill out a questionnaire.

B. Metrics

The usability and intuitiveness of the different interfaces was assessed through the efficiency, the effectiveness and the satisfaction. The efficiency was evaluated based on the total time to complete a test, the median time to find and laser a point and the time needed for the solomonization. The effectiveness depends on the full completion of the task within a reasonable time. Also the accuracy is assessed here. The satisfaction was derived from the preferred interface of the participants and compared to their actual use of the levers. To analyse the difference in subjective workload, a raw NASA-Task Load Index (raw TLI) [7] is included in the questionnaire. To interpret the participant's impression, these scores are examined in relation to the efficiency.

C. Results

Fig. 5 shows the total test times for group 1. The statistical analysis of these times shows a significant learning curve for each interface separately ($F = 6.03, p = 0.0063 < 0.05$), but no significant difference between both interfaces. The median time to laser a point and time to connect the lasered sites, did not add valuable information.

Group 2 was divided in two subgroups: groups 2A started with the 1 DoF interface and group 2B with the 2 DoF interface. This way the existing learning process could be compared for both interfaces. As Fig. 6 illustrates, more subjects had trouble completing all the tests when they started with the 2 DoF interface: in group 2B a bigger number of participants was too slow to complete all 3 tests within the set time limit. However, when the time to laser an anastomosis is compared between the interfaces, no statistically significant difference can be found. The results of the experienced surgeon are similar to those of the participants that also started with the 1 DoF interface. Interestingly, in his results he only changed the angles of the flexible tip when he was not lasering.

Based on these results no conclusive indication of superiority of either the 1 DoF or 2 DoF interface is found. When

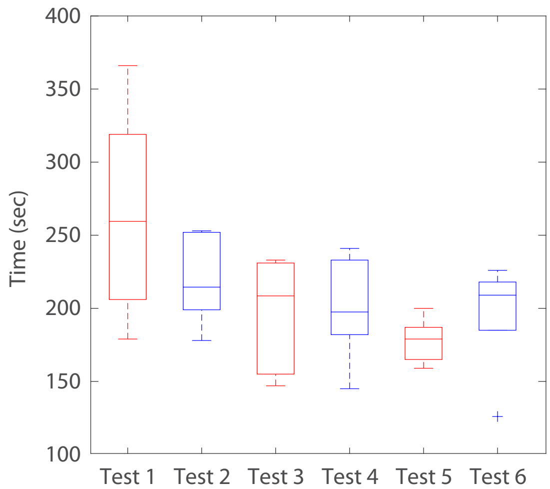

Figure 5. Total test times for the 6 particpants in group 1. In tests 1,3,5 the 1 DoF interface was used and in tests 2,4,6 the 2 DoF interface.

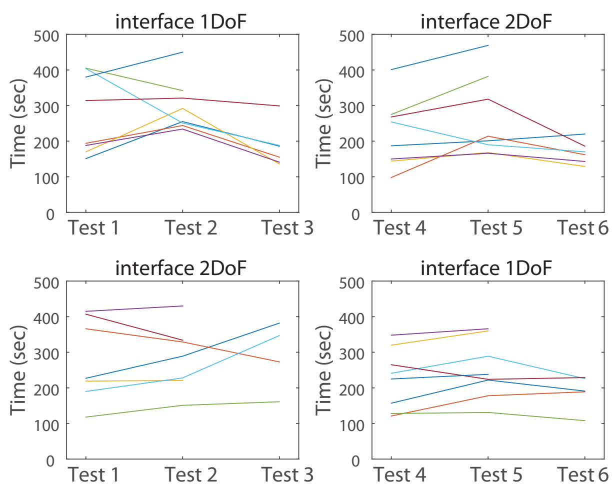

Figure 6. Total time for completion of the test for the 16 persons of group 2. top row: The group 2A that started with interface 1DoF; bottom row: the group 2B that started with interface 2DoF.

satisfaction and experienced workload of the participants is analysed, there is also no apparent preference for an interface, but, notably, participants tend to prefer the interface with which they ended the procedure. However, it is observed that participants who prefer the 2 DoF interface, barely used the additional DoF. Likely the reason for this is that the environment, consisting of two angled planes, above and opposite to the insertion point, doesn't challenge the participant to move much to the left or right. As such the added value of lever 2, that controls the left/right bending, is limited. This could explain why no statistical differences have been found between both interfaces. Therefore, in future work experiments will be conducted where the environment extend to the right and left of the insertion point as well, thus enabling a more complete comparison of different fetoscope interfaces.

IV. Conclusion

In this work a virtual reality environment was developed for the treatment of TTTS, in collaboration with clinicians. To interact with the virtual environment a 3D printed fetoscope prototype with a virtual bendable tip was designed. For this prototype different instrument control interfaces were developed. In order to find the more appropriate and advantage interface and to understand how the instrument in handled by the surgeon, the different interfaces were tested 136 times by 23 participants. The efficiency in the tests showed that a strong learning curve exists for both interfaces. The effectiveness for completing the test in time appeared to be lower for the 2 DoF interface than for the 1 DoF interface, although no statistical evidence was found to confirm this. In these first tests however, some interesting observations were made for enhancement of the fetoscope prototype, VR simulation a test procedure.

In future tests the size of the fetoscope handle (the levers in particular) will be reduced to obtain more ergonomic instrument handling. Also friction in the levers will be reduced for smoother motion. Enhancements to the VR simulation, such as a higher frame rate, will also be made. Furthermore the virtual environment will be adapted, in order to challenge the user to make more use of all available DoFs. Finally, the study population will be expanded with more users of different expertise levels.

V. Acknowledgement

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